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Description

BACKGROUND OF THE INVENTION

Field of the Invention

This Invention relates to an implantable ventricular assist device.

Description of the Prior Art

The need for an improved ventricular assist device has long been apparent. The pool of patients suffering from congestive heart failure (CHF), a progressive disease often precipitated by acute myocardial infarction, continues to grow. In 1983 alone the estimated incidence of CHF, in the course of which the heart's mechanical pumping action is severely compromised, was 400,000 in the United States. Some 2.3 million or more persons suffer from varying degrees of the disease, with the estimated annual death rate from mechanical cardiac dysfunction being 165,000. Individuals with worsening CHF who otherwise would be expected to have years of productive life ahead of them, are generally regarded as candidates for a ventricular assist system. At present, however, no generally recognized safe and effective assist device is available.

Another, patient group potentially in need of mechanical heart assistance consists of cardiac surgery patients who otherwise would die from profound refractory heart failure after removal of cardiopulmonary bypass. The intra-aortic balloon has been used to assist the circulation mechanically when other therapies have failed to allow weaning from cardiopulmonary bypass. However, half of these assisted patients die from cardiogenic shock (heart failure) despite the intra-aortic balloon. Therefore, a need exists for a more effective form of mechanical circulatory support that is capable of maintaining the systemic circulation and unloading the left ventricle while native myocardial function recovers.

A third patient group requiring mechanical heart assistance are those tachyarrhythmia patients who are at risk of sudden death due to electrical cardiac dysfunction but who also are at risk from mechanical heart failure.

In sum, it is estimated that a safe and effective implantable heart assist device could save the lives of 100,000 or more patients a year; some estimates go as high as 230,000.

In most cases, the underlying causes of the heart's weakened condition are coronary artery disease and its sequelae. The majority of these patients have a normal right ventricle but a left ventricle that has been damaged in specific regions by partial or complete arterial blockages. Ideally, then, a device designed to assist the failing heart should be able to supplement the heart's workload and also compensate for or support weakened portions of the left ventricular wall, including the apex or interventricular septum. Such a device might also incorporate pacemaker and implantable cardioverter/defibrillator technology for treating those patients who also suffer from such electrical dysfunctions as bradycardia or tachyarrhythmias.

Present ventricular assist devices (VADs) and artificial hearts have not met these needs. Existing devices generally feature blood flow pathways made from nonbiological materials. These materials (e.g., acrylics, Teflon, silicone rubber) often damage blood cells and blood proteins and produce clots, thereby presenting a generic risk of downstream lodgment (thromboembolism) in the circulatory system; attempts to coat plastics with heparin, an anticoagulant, have not been successful on a long-term basis. In fact, blood clots cause most of the deaths reported after implantation of an artificial heart or assist device. Depending on where lodgment occurs, blood clots may cause strokes, kidney failure, death (necrosis) of the intestinal wall or peritonitis, or equally severe damage to other organs.

In addition, cardiac arrhythmias may develop during ventricular assistance and adversely affect blood flow. Present assist devices do not treat these electrical dysfunctions. Other problems with existing assist devices include their substantial weight and the fact that they displace a large volume in the patient's body, which complicates implantation and increases the risk of other complications.

Another significant difficulty involves energy supply and consumption. Because current VADs lack a satisfactory implantable energy source, they must be continuously powered percutaneously. This produces a high risk of infection and generates psychological problems for the patient, who must be constantly tethered to an external power source. Some VADs now under development may offer rechargeable implanted batteries coupled with continuous electromagnetic energy transmission through the skin, the external energy source being a series of nickel cadmium batteries placed in a vest or belt. Other state-of-the-research-art VADs may allow the patient to remove the vest or belt for a brief period--up to 20-30 minutes, for example. However, greater freedom from external device dependence continues to be constrained because the implantable batteries used in these devices have a limited number of recharge cycles, poor state-of-charge indicators, poor energy density, and poor energy retention, particularly at body temperature.

Previous attempts to provide ventricular assistance have ranged from artificial hearts (e.g., the Jarvik-7), to devices which directly pump the blood via an artificial pathway inserted through the ventricular wall, to devices which exert pressure on the outside of the heart. Most frequently, pressure-exerting devices involve some form of flexible bladder within a support structure such that expansion of the bladder presses on the ventricle and facilitates expulsion of blood. See, for example, U.S. Patents 3,587,567 to Schiff; 3,371,662 to Heid et al.; 4,048,990 to Goetz; and 4,192,293 to Asrican. Another structurally related device (U.S. Patent 4,506,658 to Casile) envisions a truncated conical structure of sac-

lined rigid panels separated by contractible and expandable sections.

In all of these proposed devices, the support structure encases all or most of the heart and either pushes against or otherwise contacts the right as well as the left ventricle. This complicates ventricular assistance since most cases of heart failure are due to a failure of the left ventricle, not the right. The right ventricle, which pumps against a pressure that is typically one-fifth of that seen by the left, is generally capable of proper function without assistance. Accordingly, these devices risk preferentially pumping blood from the right ventricle, as a consequence of which blood would accumulate in the lungs and cause pulmonary edema. In recognition of this difficulty, one recent proposal (U.S. Patent 4,536,893 to Parravicini) envisions using two segmented sacs, selectively fed by a pumping fluid, to compress the ventricles separately.

Bladder systems have additional shortcomings. These include the possibility of catastrophic bladder fluid leakage, a propensity for damaging the heart surface due to poor fixation and/or rubbing of the bladder against the heart's surface, and the unnatural convex form presented to the heart's surface during systolic bladder expansion.

Another type of cardiac assist system is designed to compress all or part of the heart by alternately tightening and releasing a circumferential compression band. For example, one proposed system for body organs (U.S. Patent 4,304,225 to Freeman) involves a flexible strap which is fixed to a contoured plastic block and which would pass across the back of the heart. In response to electrical pulses, a motor assembly would alternately reel in and release the flexible strap, thereby forcing fluid from the subject organ. One liability of this approach is that a pressure of between 2660 Pa (20 mm Hg) and 9300 Pa (70 mm Hg) in the volume under the strap would pump blood from the right ventricle but not the left, since 9300 Pa (70 mm Hg) or more is required for blood to exit the left ventricle into the aorta. As with the bladder-type devices discussed above, such a preference could lead to a buildup of blood in the lungs, producing severe pulmonary complications.

U.S. Patent 4,583,523 to Kleinke and Freeman illustrates a heart assist mechanism with some similarities to the present invention. However, there are numerous differences. For example, Patent 4,583,523 compresses the aorta, not the left ventricle, and it compresses during the diastolic phase of cardiac contraction instead of the systolic phase. Furthermore, it has no means to continuously control the depth of stroke. Specifically, there is no means to monitor the adequacy of left ventricular stroke volume.

SUMMARY OF THE INVENTION

This invention relates to an implantable ventricular assist device having the features of appended claims 1 or 2.

One or more compression mechanisms may cooperate with a tension band surgically placed through the interventricular muscle wall of the heart; the opposite ends of the tension band would be connected to a rigid support external to the heart, with one or more pressure plates positioned between the block and the heart. In a further variation, the tension bands would be rigidly fixed to the compression mechanisms, which, when closed by the operating means, would reduce the circumference of the band opening and thereby squeeze the heart.

The operating mechanism, for cyclically actuating the compression mechanisms, includes a motor for inducing controlled reciprocating motion plus a means for mechanically translating this motion into pressure-plate compression. The invention includes a brushless, battery-powered D.C. motor which utilizes an annular energizing coil and magnets to drive a roller screw. The roller screw engages a bellows pusher (or a similarly functioning component, such as a rolling diaphragm), which in turn is connected, via fluid-filled elastomeric tubing, with a compression housing that contains a second bellows. When pressure is exerted on the first bellows by the roller screw, the fluid coupling transmits pressure to the second bellows, to which is attached a driving wedge that engages the mounted compression mechanisms and thereby aids ventricular compression.

The fluid coupling permits the cylindrical motor housing to be implanted in a posterior mediastinum position parallel to the descending aorta, while the pumping mechanism housing is positioned in the left chest, adjacent the left ventricle. In a second embodiment of this invention, the motor housing and the pumping mechanism housing would form an integral unit, with the nut of the roller screw bonded to the driving wedge. In both embodiments, linear movement of the roller screw mechanically governs the degree of pressure-plate movement (compression and return) in the compression axis.

To allow the pumping mechanism housing (first embodiment) or the integral motor/pump housing (second embodiment) to float with the natural movement of the heart, the assembly may be placed in a lubricant-filled sac. At the same time, tethering the assembly to, for example, the ventral surface of the sac would limit the degree of motion.

The implanted, programmable control mechanism, for regulating actuation of the operating mechanism, utilizes input provided in part from device motion sensors, an arterial blood pressure sensor, blood flow sensors, heart rate-sensing (R-wave sensing) electrodes, and/or ECG morphology-sensing electrodes positioned in the heart and/or on the compression mechanisms. The associated pacemaker unit, implantable cardioverter/defibrillator and energy storage device, transcutaneous programmer/interrogation unit, and internal biological recorder are of types known to those skilled in the art.

An object of the invention is to provide a new and improved biocompatible ventricular assist device which

(1) can be completely and readily implanted in the patient's body, external to the heart and to blood flow pathways; and (2) is relatively simple, light-weight, and compact.

Another object of this invention is to provide such a ventricular assist device which also treats electrical dysfunctions (atrial and ventricular, bradycardic and tachyarrhythmic) to facilitate synchronous pumping, thereby assuring an adequate flow of oxygenated blood.

An object of this invention is also to provide means for transcutaneous programming of operating parameters and transcutaneous interrogation as to prior operations.

BRIEF DESCRIPTION OF DRAWINGS

Figure 1 is a schematic block diagram of a first embodiment of a ventricular assist device in accordance with the invention;

Figure 2a is a schematic general front elevational view of the upper portion of a human body in which is implanted the first embodiment of the ventricular assist device in accordance with the invention;

Figure 2b is a schematic general plan view as seen along the line 2b-2b in Figure 2a;

Figure 3a is a schematic view of a second embodiment of the invention in a first operating position;

Figure 3b is a schematic view showing the embodiment of Figure 3a in a second operating position;

Figure 4a is an enlarged front elevational view of a direct cardiac pumping mechanism of the first embodiment of the invention;

Figure 4b is a separate front view of a part of the pumping mechanism shown in Figure 4a, illustrating first and second operating positions;

Figure 4c is a top view as seen along the line 4c-4c in Figure 4a;

Figure 5 is a schematic view of a third embodiment of the invention.

DETAILED DESCRIPTION

Figure 1 discloses a block diagram of one embodiment of a biocompatible ventricular assist and arrhythmia control device 10 in accordance with the invention, hereafter referred to as the ventricular assist device, it being understood that numerous other variations of the invention are, of course, possible. As disclosed in Figure 1, the ventricular assist device 10, which operates, on demand, in synchronism with a heart left ventricle 12, comprises an implantable subsystem 14 and a subsystem 16 external to, and without penetrating, a patient user's skin 18. The implantable subsystem 14 includes a direct cardiac pumping mechanism 20 and a motor housing 22, both outlined by alternating dashes and asterisks. The motor housing 22 includes a motor 24 and a rotary-to-linear motion converter 26 which mechanically initiates (directly or indirectly) the inward ventricle-assist motion of the pumping mechanism 20 when the left ventricle 12 begins to contract, limits and controls the degree of mechanical compression, and terminates the compression stroke so that the pumping mechanism 20 may return to its original outward position as the ventricle refills. The pumping mechanism 20 and motor housing 22 also include sensors which provide input to a device control system 28, within an electronic module 30.

The electronic module 30, as indicated in broken lines, includes, in addition to the control system 28, a rechargeable power supply 32 and an energy storage device 34, which may be one or more capacitors. The electronic module 30 further includes a cardiac pacer unit 36 and a cardioverter/defibrillator unit 38 for arrhythmia control, in part to promote operation of the pumping mechanism 20 in synchronism with the left ventricle 12; a biological signal recorder 40; and a patient alarm device 42. Another feature of the implantable subsystem 14 is an emergency manual pumping mechanism 44, located outside the electronic module 30 and connected to the direct cardiac pumping mechanism 20.

The external subsystem 16 includes a power supply 46, for charging the internal power supply 32 transcutaneously, and noninvasive combined programmer/interrogation units 48, 50.

Figures 2a and 2b show the ventricular assist device 10, as represented by the block diagram of Figure 1, implanted in an upper portion of a human body 100 for assisting the left ventricle 12 of a heart 102 in the pumping of blood from the heart, through the aorta 104, and to the arterial system. It is to be understood that the disposition of the various parts of the ventricular assist device 10 as shown in Figures 2a, 2b and subsequent figures is merely for purposes of illustration and that other location arrangements may be used.

The pumping mechanism 20 (Figure 2a) engages the walls of the left ventricle 12 and is disposed in part between the left ventricle and the left lung 106. A manually operable button 108 of the manual pumping mechanism 44 is positioned between two adjacent ribs 110, with the button protruding under the skin 18 to facilitate emergency use by the patient user or by another person. The cylindrical motor housing 22 (in outline) of the ventricular assist device 10 is disposed in a posterior mediastinum position parallel to the descending aorta 112.

As is best shown in Figures 4a, 4b and 4c, the pumping mechanism 20 includes triaxial lateral pressure plate assemblies 118 around the heart 102, for engaging and compressing the left ventricle 12 in synchronism with native or pacemaker-initiated pumping action. Each pressure plate assembly 118 includes a pressure plate 120 formed of a spring-tempered, biocompatible, inert metal, such as the nickel alloy MP35NR (an alloy of nickel, cobalt, chromium, and molybdenum). Each pressure plate 120 is attached to a driver arm 122 or 124 by way of an axle/bearing mount 126 so that the pressure plate may follow, within specified limits, the natural movement of the heart. Each driver arm 122 or 124 is mounted on an actuator housing 128, pivoting on a light-weight, high-performance bearing 130, which, like the bearing in

the axle/bearing mount 126, consists of a tubular lining of, woven Teflon/Dacron fabric and an inner wound fiberglass epoxy resin matrix. The driver arms 122 and 124 and the actuator housing 128 consist of a biocompatible metal compound, such as Ti6Al4V (titanium, aluminium, and vanadium). Driver arms 122 and 124 are engaged by wedge followers 132, each of which includes a roller 134 mounted on a follower bearing 136 (of similar construction to arm bearing 130).

The above pumping or compression mechanism 20 is readily adapted to varying combinations of pressure plate assemblies 118. For example, triaxial lateral placement could be supplemented with a fourth, smaller plate (not shown) positioned on the right ventricle 138 (Figure 2a), or with an apical plate (not shown) for supporting and supplying compressive force to the left ventricular apex 140.

It should also be perceived that other embodiments of the pumping mechanism 20 are possible. For example, in an embodiment of the invention as shown in Figures 3a and 3b, a ventricular assist device 10" includes a pressure plate assembly 118" positioned on a lateral wall of a left ventricle 12" of a heart 102". However, instead of the pressure plate assembly 118" being opposed by other left ventricular pressure plate assemblies, an intermediate portion of a titanium or platinum tension band 300 is surgically placed in an interventricular muscle wall 302 between the left ventricle 12" and a right ventricle 138". Opposite ends of the tension band 300 are fixed to a rigid support (e.g., a curved plate) 304 implanted in adjacent body tissue so as to be essentially immovable. A separate defibrillating electrode 306 is mounted on the outside of the right ventricle 138", for providing cardioverting/defibrillating current to the inner surface of the pressure plate assembly 118".

Figure 3b illustrates the action of the ventricular assist device 10" when the pressure plate assembly 118" is moved to the left by a pumping mechanism of the type shown in Figures 4a. The pressure plate assembly 118" and the rigid structure 304 separate, resulting in constriction of the left ventricle 12" during ventricular contraction. The advantage of this embodiment of the invention is that it compensates for weakness of the interventricular muscle wall 302 and, by encompassing the ventricle 12", gives generalized support to the contracting ventricle.

In the further embodiment of the invention shown in Figure 5, a ventricular assist device 10"" includes one or more encircling bands 300' (only one shown) positioned around, for example, a left ventricle 12"". As in Figures 3a and 3b, intermediate portions of the bands 300' are surgically implanted in an interventricular wall 302' between the left ventricle 12"" and a heart right ventricle 138"". Further, opposite ends of the bands 300' are connected to a suitable operating mechanism by being rigidly fixed (e.g., welded) to two pressure plates 120"". Thus, when the pressure plates 120"" close, the bands 300' are moved from solid to broken line positions, thereby compressing the left ventricle 12"".

Referring again to Figures 1 and 2, the functions of the electronic module 30 will now be discussed. While the description refers primarily to the preferred embodiment of the invention, it is to be understood that the description, with certain modifications, is also applicable to other possible embodiments of the invention.

The electronic module casing houses, in part, one or more electronic circuit packs 52 and the rechargeable power supply 32, the latter including four or more AA batteries 166 and the energy pickup coil 116. The electronic circuit packs 52 contain the various units shown in Figure 1, including the control system 28, energy storage device 34, cardiac pacer unit 36, cardioverter/defibrillator 38, biological recorder 40, and alarm device 42.

The control system 28 may utilitze a variety of sensing strategies to provide optimal mechanical pumping assistance in any of three basic modes: normal left ventricular assist mode, ventricular arrhythmia/asystole mode, and failsafe/standby mode. During normal assist mode, the pressure plate assemblies 118 assist in ventricular compression as needed to maintain sufficient blood flow. In the event of ventricular tachycardia, ventricular fibrillation, or asystole, cardioversion/defibrillation or pacing is attempted, as appropriate. Should cardioverting/defibrillating energy be needed, the pressure plate assemblies 118 would first compress the heart 102 so as to eject blood from the organ and thereby decrease the cardioversion/ defibrillation energy threshold. If this electrical therapy is unsuccessful, the pumping mechanism 20 responds by compressing the left ventricle 12 at a rate of approximately 72 beats per minute and with sufficient compression depth to maintain systolic pressure of about 11970-15960 kPa (about 90-120 mmHg). In failsafe mode, the pressure plate assemblies 118, in response to failure of the implanted system, would permit natural movement of the heart 102; the manual pumping mechanism 44 could then be used, if needed, by the patient user or a bystander.

The control system 28 utilizes input from a variety of sensors. For example, data from rate-sensing electrodes 154 (Figure 2a) enable the control system to coordinate pressure plate compressions with R-waves and to provide A-V synchrony for optimized blood flow, if desired. Typically, three Hall-effect sensors (not shown) in the brushless DC motor 24, in combination with the motor's eight magnets, may be used to determine the position of the pressure plate assemblies 118 by sensing rotation of the motor's rotor, which can be translated into linear displacement of the roller screw's reciprocating shaft 172. Alternatively, exact displacement of the reciprocating shaft 172 can be determined by integrating the angular velocity of the rotor, which is directly proportional to the back electromotive force (EMF) of the motor 24. The pressure plate closing velocity and force also can be readily controlled, if desired, by varying the torque of the motor 24 by a servo mechanism 24s (shown schematically in Figure 2a.

By analyzing such information the control system 28 can calculate and adjust such variables as ejection frac-

tion, aortic blood pressure, stroke volume (cc/beat), and blood flow rate (cc/sec). For example, the heart 102 may be allowed to fill to any left ventricular end diastolic volume, depending on left atrial venous return. Then, based on plate position data, the current of motor 24 can be adjusted to obtain a fixed final ejection position (end systolic volume) in the compression stroke. As another option, a fixed current can be applied for a given time to the motor 24, which results in a fixed torque and force to the pressure plate assemblies 118. This will result in variable end compression positions, depending, for example, on filling time and volume. On the other hand, varying levels of force can be applied to the pressure plate assemblies 118, with sensors then reading the resultant blood pressures and enabling the control system 28 to adjust the force or the end pressure plate position to maintain a programmed aortic blood pressure. Aortic root blood pressure may be sensed using a solid-state pressure transducer (not shown) positioned in the aortic wall. As yet another approach, over a specified number of beats pressure plate work can be gradually added, as a supplement to natural heart function, until aortic systolic pressure reaches a preprogrammed level. Using servocontrol techniques, the amount of pressure plate assistance will automatically adjust to the level required by the natural heart 102 to maintain the desired aortic pressure. Stroke volume can also be assessed by measuring impedance across the electrodes 144, since impedance is related to blood volume within the heart 102.

The control system 28 also contains various automatic self-test features. For example, each time the energy storage device 34 supplies energy to the motor 24 for assisting blood circulation or to the cardioverter/defibrillator unit 38 for tachyarrhythmia conversion, the internal voltage of the batteries 166 is compared to a threshold value in a battery test circuit 54 (Figure 1). If the battery voltage drops below the threshold value, the battery test circuit 54 enables the patient alarm 42, which may utilize a piezoelectric crystal to produce an audio tone. The patient alarm 42 can also be enabled each time a tachyarrhythmia is detected by the control system 28, thereby warning the patient that he is about to receive a defibrillation or cardioversion pulse.

The control system 28 also includes a real-time electrophysiology/hemodynamic (EH) evaluation mode circuit 56. The EH mode, in which arrhythmia detection by the bipolar electrodes 154 (Figure 2a) is inhibited, is initiated by command from the programmer 48. The cardiac pacer unit 36 then is placed into the VVT mode (i.e., ventricular pacing, ventricular sensing, pulse triggered by sensed event), but with standard electrophysiology equipment providing simulated R-waves to the programmer 48 via a telemetry link. During this mode, the internal recorder 40 also transmits electrocardiogram (ECG) data, ventricular motion data, and blood flow rate data to the programmer 48. By using the EH mode, the patient's risk of arrhythmia genesis and the most effective treatment modes can be determined, and pumping settings of the ventricular assist device 10 can be adjusted to reduce energy requirements and optimize blood flow and/or pressure.

The cardiac pacer unit 36, cardioverter/defibrillator unit 38, and biological recorder 40, as well as the energy storage device 34, are of types known to those skilled in the art. The cardiac pacer unit 36 is noninvasively programmable, has automatic gain control of the input stages, and provides ventricular, atrial, dual chamber, and antitachycardia pacing as required. The cardioverter/defibrillator unit 38 is noninvasively programmable, has automatic gain control, and is energized from the energy storage device 34 to provide synchronized defibrillation or cardioversion pulses as required.

The cardiac pacer 36 and cardioverter/defibrillator 38, in conjunction with the control system 28 and signals from the cardiac electrodes 144 and 152 of the pressure plate pumping assemblies 118 and from the atrial cardiac electrodes 154, typically diagnose tachyarrhythmias using three criteria: rate, morphology, and rate acceleration. (Additional detection parameters can include rate stability and sustained high rate.) For this purpose, a rate-detection circuit 58 (Figure 1) of the control system 28 counts the R-waves as detected by the bipolar electrodes 152, for example, and compares this rate with two or more programmed rate thresholds. A morphology-detection circuit 60 examines the shape of transcardiac signals sensed by rectangular electrodes 144 and determines when an absence of isoelectric time occurs, which is characteristic of tachyarrhythmias. Further, an acceleration-detection circuit 62 compares the rate of change of the heart rate with a programmed threshold, rapid acceleration normally being associated with treatable tachyarrhythmias. For example, during exercise-induced sinus tachycardia, rate accelerates typically at 20 beats per minute per second, whereas spontaneous ventricular tachycardia typically results in a rate acceleration of about 90 beats per minute per second. Tachyarrhythmias can also be detected by motion sensors because, for example, the ventricle 12 will quiver rather than contract rhythmically during ventricular fibrillation. Combinations of these criteria identify various types of arrhythmic conditions, and for each type an individual treatment sequence can be programmed into the control system 28. Also, in the event of ventricular arrhythmias that cannot be controlled by the arrhythmia-control units 36 and 38, the control system 28 can be programmed to revert to an asynchronous ventricular assist mode to ensure adequate, or at least life-supporting, blood flow.

Bradycardia diagnosis may be accomplished using signals from the atrial bipolar electrodes 154 (Figure 2a) on a beat-by-beat basis. Other rate-responsive physiological signals may also be used. These signals include venous blood temperature, oxygen content of the blood, blood pH, respiration rate, muscle activity, and QRS duration. If the heart 102 goes into bradycardia and pacing is required, one optional control mode could be to have the pacer 36 search for the optimum pacing rate as determined by measuring cardiac output versus rate.

Output pulses to the heart 102 from the cardiac pacer unit 36 are typically in the microjoule energy range and are at rates typical of cardiac pacing (60-120 pulses per minute) for bradycardia, or at very high rates (150-1500 pulses per minute) to treat tachyarrhythmias. Output pulses from the cardioverter/defibrillator unit 38 are typically in the range of 0.1 joules to 50 joules, and are either asynchronous or synchronous with the R-wave. In the event cardioversion/defibrillation is required, the control system 28 would ensure full compression of the pressure plate assemblies 118 before countershock delivery, thereby minimizing the volume of blood in the heart and achieving a lower cardioversion/defibrillation energy threshold.

The internal biological recorder 40 records and stores electrogram events, such as tachyarrhythmia onset and conversion; device status, such as battery condition; ventricular motion; and blood flow rate. The recorder 40 may utilize a delta-modulation scheme to achieve analog-to-digital conversions of the signals at a typical bit/second rate of 200. The delta-modulated data can then be stored, for example, in a CMOS RAM. On command of the programmer unit 48, the recorder 40 then can delta-demodulate the stored data to produce an analog voltage which can be transmitted to the interrogation unit 50 by way of a telemetry link 64. The recorder 40 can telemeter on-line data as well as stored data, if desired.

Referring again to Figure 1, the functions of the transcutaneous power supply 46 and the programmer/interrogation units 48, 50 will now be further described. The external transcutaneous power supply 46 comprises about 15 power cells (not shown), such as the batteries 166, in a "C" configuration connected in series. The external power supply 46, which weighs about two pounds and is worn by the patient in a belt or vest (not shown), keeps the internal power supply 32 fully charged while providing power for the internal subsystem 14 for at least 10 hours without recharging. At nominal conditions, the transcutaneous power supply 46 can operate the internal subsystem 14 up to a day before being recharged or replaced with a fully charged new power supply belt or vest.

A telemetry link 66 permits noninvasive programming and interrogation of the internal subsystem 14, with communication from the programmer 48 to an internal device 68 in the control system 28 being accomplished with a digital radio frequency (RF) technique. Communication from the internal device 68 to the programmer 48 can be by either an RF channel or an audio channel, the latter using a piezoelectric speaker (not shown). Communication on either channel can be digital for data transmission, or analog for transmission of real-time or recorded electrocardiograms, for example.

The ventricular assist devices 10-10"' in accordance with the invention are considered advantageous in that each normally should be capable of supporting full cardiac output, if necessary. Each device 10-10"' is capable, for example, of supporting a failed left ventricle 12-12"' with a continuous output of 7-10 liters per minute without having to exceed a pump rate of 120 beats per minute into a mean arterial pressure of 15960 Pa (120 mmHg) (which might be associated, typically, with a peak arterial pressure of 20000 Pa (150 mmHg)) and a maximum filling pressure of about 2000 Pa (15 mmHg). In addition, the rate of pressure rise and fall due to pumping assistance will be low enough to avoid excessive blood turbulence, hemolysis, or blood cavitation. Furthermore, the pressure plate assemblies 118-118"' or resilient bands 300-300', which are external to the ventricular cavities of the heart 102-102"', do not impede venous return, compromise any organ system, or degrade blood circulation in the coronary arteries. The devices 10-10"' also eliminate the need, present in certain prior known ventricular assist devices, for a separate compliance chamber (displaced volume compensation for cycle changes in volume between pumping sacs and encapsulating shells), which may be compromised by fibrous tissue encapsulation and which requires periodic replacement of gas which has diffused through the compliance chamber materials. The invention also eliminates the need for any valves, which have inherent and well-documented problems in prior known cardiac assist devices.

Each of the ventricular assist devices 10-10"' is also advantageous in that it reduces the total weight of all implanted components, when compared to the total weight of known prior art ventricular assist devices. The overall weight of the components, including batteries 166, is in a range of 400-500 grams, which represents a weight reduction by a factor of four from known prior art systems that generally weigh 1500-2000 grams.

Another advantage of ventricular assist device 10 is that the fluid coupling between the bellows 180 and 184 constitutes a failsafe mechanism whereby the pumping mechanism 20, in the event of motor failure, does not restrict the natural movement of the heart 102. Additionally, several embodiments of the invention would permit separate implantation of the motor housing 22, with only the pumping mechanism 20 implanted adjacent the heart. Furthermore, for all ventricular assist devices 10-10"', the electronic module 30 need not be implanted near the pumping mechanism 20-20', but may be remotely implanted. This modular construction facilitates replacement of components, should any fail, and also allows flexibility in determining the optimum implant sites for the individual patient's physiology.

In summary, new and improved biocompatible ventricular assist and arrhythmia control devices 10-10" have been disclosed. For example, device 10 can be completely and readily implanted in the body of a patient user, eliminating the need for tethering to an external power supply; is of relatively simple, light-weight, and compact construction; requires only a small amount of energy for reliable operation over an extended period of time; incorporates a control mechanism for determining left ventricular stroke volume and for changing compressive force, as needed, to assure an adequate supply of oxygenated blood; and includes bradycardic and tach-

yarrhythmic control features, which will facilitate device operation in synchronism with left ventricular contraction. In addition, the rechargeable power supply 32 of the device 10 can be readily recharged transcutaneously, and the device can be noninvasively programmed and interrogated. The device 10 places no foreign, nonbiological materials in contact with the blood flow, thereby avoiding the documented danger of clotting and associated body malfunctions. The device 10 also is capable of providing effective mechanical circulatory support to the ventricle 12 of the heart 102 while myocardial function recovers postoperatively.

It is intended that all matter contained in the above description and shown in the accompanying drawings be interpreted not in any limiting sense, but as demonstrative. It is also to be understood that the following claims are intended to cover all of the generic and specific features of the invention.

Claims

1. A ventricular assist device which can be implanted in a patient user exterior to the heart (102"), which comprises:

   - a pumping means (20) which includes one or more movable ventricle compression assemblies (118") for engaging an outer surface of at least one heart ventricle (12");
   - operating means for cyclically actuating the one or more compression assemblies, such that the ventricle is, first, compressed to aid blood ejection therefrom, and second, released to permit refilling;
   - control means (28) for regulating actuation of the operating means; and
   - an electrical power source (32);

   characterized in that
   the device also includes a means (40) for recording data produced during the operation of said ventricular assist device, the recording means being implantable and capable of transcutaneous interrogation; and that the pumping means (20) also includes:

   - a rigid support member (304) external to the heart;
   - at least one resilient band (300) having an intermediate portion surgically implantable in an interventricular wall (302) of the heart, the band having opposite ends which connect to the rigid support member (304); and
   - one or more of the movable ventricle compression assemblies (118") positioned between the rigid support member (304) and the resilient band (300).

2. A ventricular assist device which can be implanted in a patient user exterior to the heart (102"), which comprises:

   - a pumping means (20) which includes one or more movable ventricle compression assemblies (118") for engaging an outer surface of at least one heart ventricle (12");
   - operating means for cyclically actuating the one or more compression assemblies, such that the ventricle is, first, compressed to aid blood ejection therefrom, and second, released to permit refilling;
   - control means (28) for regulating actuation of the operating means; and
   - an electrical power source (32);

   characterized in that
   the device also includes a means (40) for recording data produced during the operation of said ventricular assist device, the recording means being implantable and capable of transcutaneous interrogation; and
   that the pumping means (20) also includes:
   at least one resilient band (300') having an intermediate portion surgically implantable in an interventricular wall (302') of the heart and having end portions fixed to two movable ventricle compression assemblies (120"') such that actuation of the compression assemblies constricts the at least one resilient interventricular band and thereby compresses the ventricle.

Patentansprüche

1. Kammer-Unterstützungsgerät, welches einem das Gerät benutzendem Patienten außerhalb des Herzes (102") implantiert werden kann, mit:

   - einer Pumpeinrichtung (20), welche eine oder mehrere bewegbare Kammer-Kompressionsbaugruppen (118") zur Beaufschlagung einer äußeren Fläche mindestens einer Herzkammer (12") aufweist;
   - einer Betätigungseinrichtung zum zyklischen Auslösen der einen oder mehrerer Kompressionsbaugruppen, derart, daß die Herzkammer erst komprimiert wird, um das Herausdrücken des Blutes zu unterstützen, und danach gelöst wird, um ein Auffüllen zu erlauben;
   - einer Steuereinrichtung (28), welche das Auslösen der Betätigungseinrichtung regelt; und
   - einer elektrischen Stromquelle (32);

   dadurch **gekennzeichnet**,
   daß das Gerät ferner eine Einrichtung (40) zur Aufzeichnung von Daten aufweist, welche während des Betriebs des Kammer-Unterstützungsgerätes erzeugt werden, wobei die Aufzeichnungseinrich-

tung implantierbar ist und für eine Abfrage durch die Haut hindurch geeignet ist; und
daß die Pumpeinrichtung (20) ferner aufweist:

- ein außerhalb des Herzes befindliches starres Stützglied (304);
- mindestens ein elastisches Band (300), welches einen mittleren Abschnitt hat, welcher chirurgisch in eine Zwischenkammer-Wand (302) des Herzes implantierbar ist, wobei das Band gegenüberliegende Enden besitzt, welche mit dem starren Stützglied (304) verbunden sind; und
- eine oder mehrere der bewegbaren Kammer-Kompressionsbaugruppen (118"), welche zwischen dem starren Stützglied (304) und dem elastischen Band (300) angeordnet sind.

2. Kammer-Unterstützungsgerät, welches einem das Gerät benutzendem Patienten außerhalb des Herzes (102") implantiert werden kann, mit:

- einer Pumpeinrichtung (20), welche eine oder mehrere bewegbare Kammer-Kompressionsbaugruppen (118") zur Beaufschlagung einer äußeren Fläche mindestens einer Herzkammer (12") aufweist;
- einer Betätigungseinrichtung zum zyklischen Auslösen der einen oder mehrerer Kompressionsbaugruppen, derart, daß die Herzkammer erst komprimiert wird, um das Herausdrücken des Blutes zu unterstützen, und danach gelöst wird, um ein Auffüllen zu erlauben;
- einer Steuereinrichtung (28), welche das Auslösen der Betätigungseinrichtung regelt; und
- einer elektrischen Stromquelle (32);

dadurch **gekennzeichnet**,
daß das Gerät ferner eine Einrichtung (40) zur Aufzeichnung von Daten aufweist, welche während des Betriebs des Kammer-Unterstützungsgerätes erzeugt werden, wobei die Aufzeichnungseinrichtung implantierbar ist und für eine Abfrage durch die Haut hindurch geeignet ist; und
daß die Pumpeinrichtung (20) ferner aufweist:
mindestens ein elastisches Band (300'), welches einen mittleren Abschnitt hat, welcher chirurgisch in eine Zwischenkammer-Wand (302') des Herzes implantierbar ist und das Band Endabschnitte besitzt, welche an zwei bewegbaren Kammer-Kompressionsbaugruppen (120") derart befestigt sind, daß ein Auslösen der Kompressionsbaugruppen zumindest das eine elastische Zwischenkammer-Band zusammenzieht und damit die Kammer komprimiert.

Revendications

1. Dispositif d'assistance ventriculaire pouvant être implanté chez un patient à l'extérieur du coeur (102") et qui comprend:
des moyens de pompage (20) qui comprennent un ou plusieurs ensembles de compression ventriculaire mobiles (118") pour la coopération avec la surface extérieure d'au moins un ventricule cardiaque (12");
des moyens opérants pour actionner cycliquement le ou les ensembles de compression de telle sorte que le ventricule est d'abord comprimé pour faciliter l'éjection du sang à partir de celui-ci, et il est ensuite relâché pour permettre à nouveau le remplissage;
des moyens de commande (28) pour réguler l'actionnement des moyens opérants et
une source de puissance-électrique (32); caractérisé en ce que
le dispositif comprend également des moyens (40) pour enregistrer des données produites pendant le fonctionnement de ce dispositif d'assistance ventriculaire, des moyens d'enregistrement pouvant être implantés et étant aptes à l'interrogation transcutanée; et
en ce que les moyens de pompage (20) comprennent également:
un élément de support rigide (304) extérieur au coeur;
au moins une bande élastique (300) ayant une portion intermédiaire implantable chirurgicalement dans une paroi interventriculaire (302) du coeur, la bande présentant des extrémités opposées qui se raccordent sur l'élément de support rigide (304); et
un ou plusieurs des ensembles de compression Ventriculaire mobiles (118") positionnés entre l'élément de support rigide (304) et la bande élastique (300).

2. Dispositif d'assistance ventriculaire pouvant être implanté chez un patient à l'extérieur du coeur (102") et qui comprend:
des moyens de pompage (20) qui comprennent un ou plusieurs ensembles de compression ventriculaire mobiles (118") pour la coopération avec la surface extérieure d'au moins un ventricule cardiaque (12");
des moyens opérants pour actionner cycliquement le ou les ensembles de compression de telle sorte que le ventricule est d'abord comprimé pour faciliter l'éjection du sang à partir de celui-ci, et il est ensuite relâché pour permettre à nouveau le remplissage;
des moyens de commande (28) pour réguler l'actionnement des moyens opérants et
une source de puissance électrique (32); caractérisé en ce que

le dispositif comprend également des moyens (40) pour enregistrer des données produites pendant le fonctionnement de ce dispositif d'assistance ventriculaire, des moyens d' enregistrement pouvant être implantés et étant aptes à l'interrogation transcutanée; et

en ce que les moyens de pompage comprennent également:

au moins une bande élastique (300') ayant une portion intermédiaire implantable chirurgicalement dans une paroi interventriculaire (302') du coeur, la bande présentant des extrémités fixées à deux ensembles de compression ventriculaire mobiles (120") de telle sorte qu'un actionnement des ensembles de compression contracte au moins ladite une bande interventriculaire et comprime ainsi le ventricule.

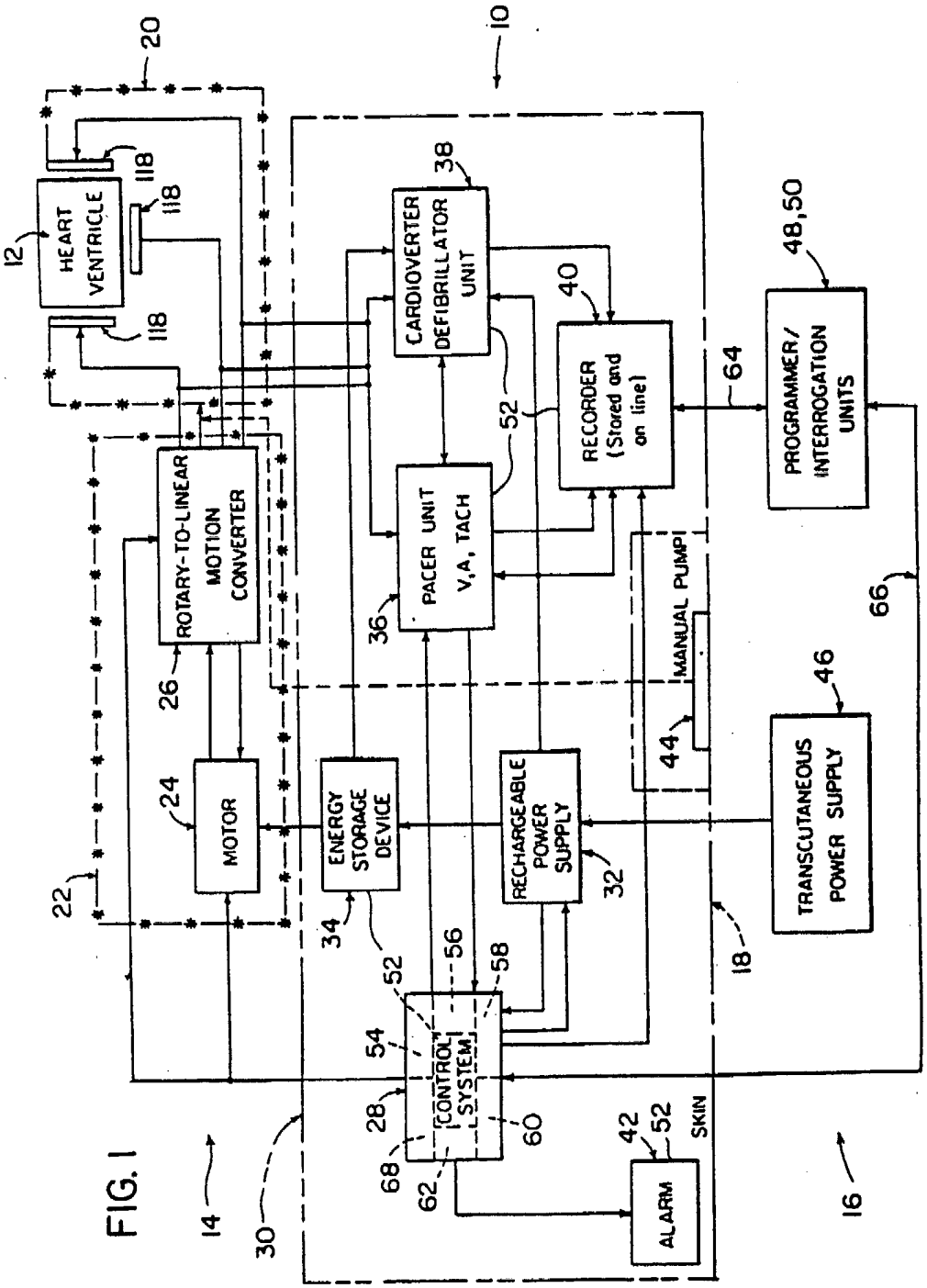
10
20
12
HEART VENTRICLE
118
118
118
38
CARDIOVERTER DEFIBRILLATOR UNIT
40
RECORDER (Stored and on line)
48,50
PROGRAMMER/ INTERROGATION UNITS
64
52
ROTARY-TO-LINEAR MOTION CONVERTER
PACER UNIT V,A, TACH
36
MANUAL PUMP
66
26
24
MOTOR
ENERGY STORAGE DEVICE
RECHARGEABLE POWER SUPPLY
32
44
46
TRANSCUTANEOUS POWER SUPPLY
22
34
52
56
58
18
54
CONTROL SYSTEM
28
60
42
52
SKIN
68
62
ALARM
14
30
16

FIG. 1

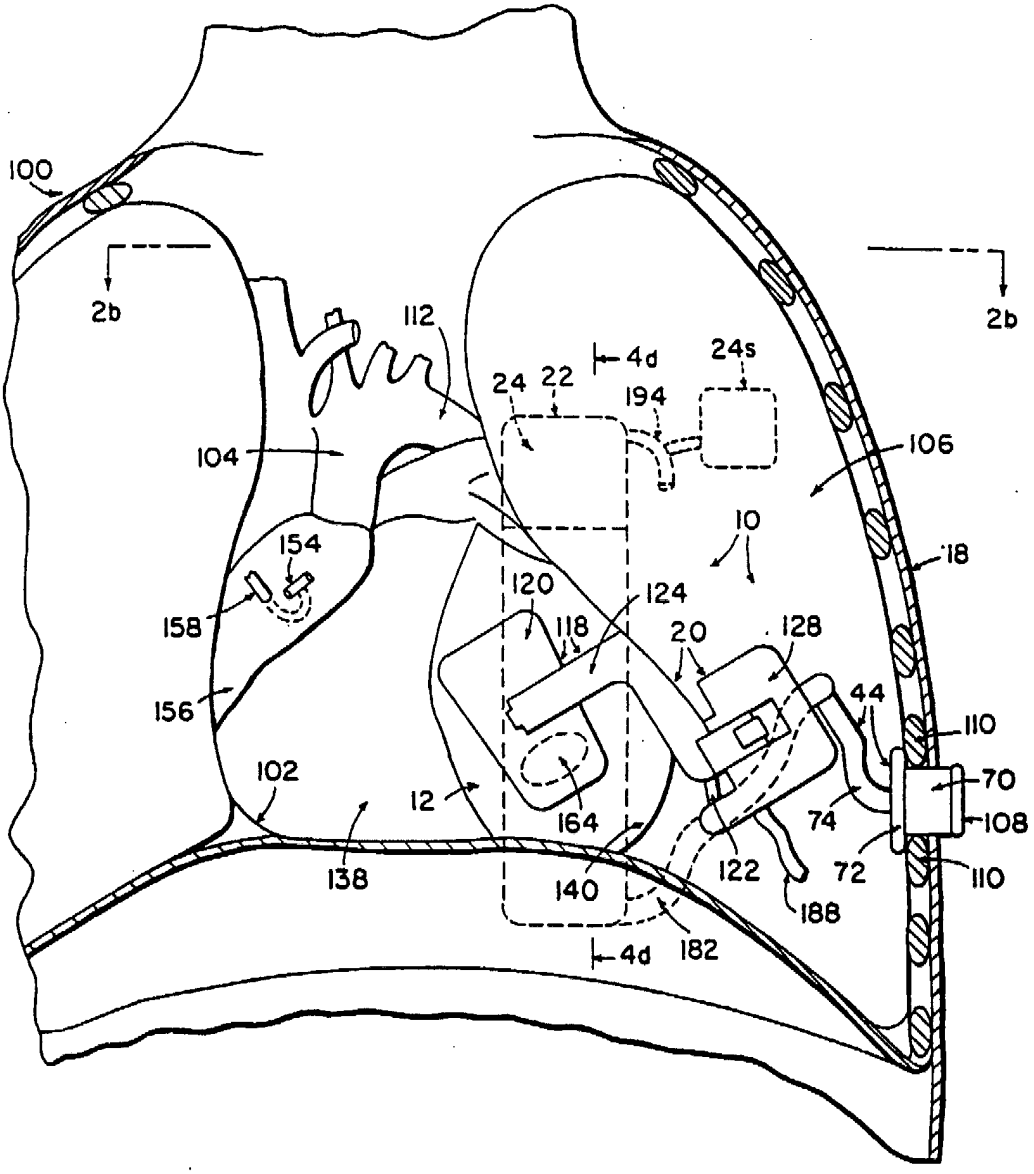
100
2b
2b
112
4d
24s
24
22
194
106
104
10
18
154
120
124
158
118
20
128
44
156
110
102
12
70
164
74
108
138
140
122
72
110
188
4d
182

FIG. 2a

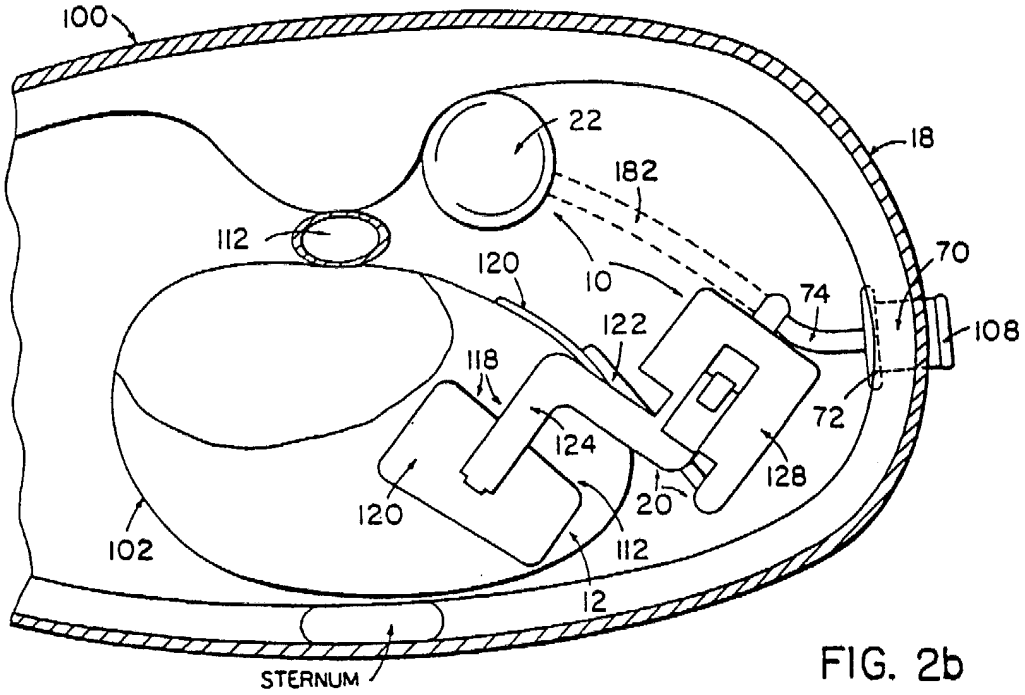
100
22
182
18
112
120
10
70
74
108
122
118
72
124
128
120
20
102
112
12
STERNUM

FIG. 2b

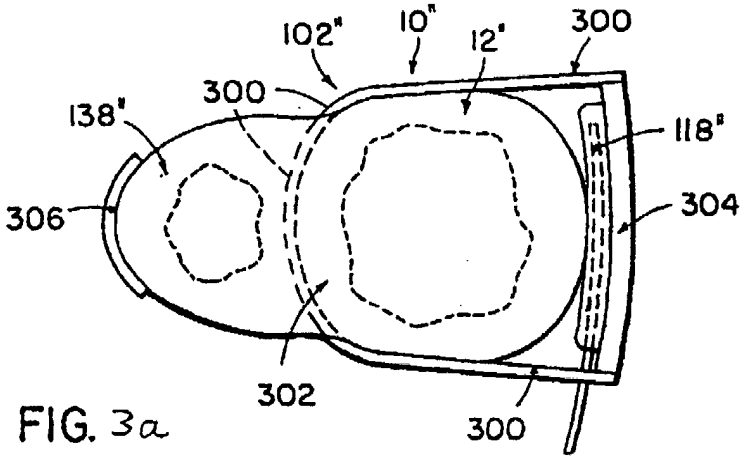

FIG. 3a

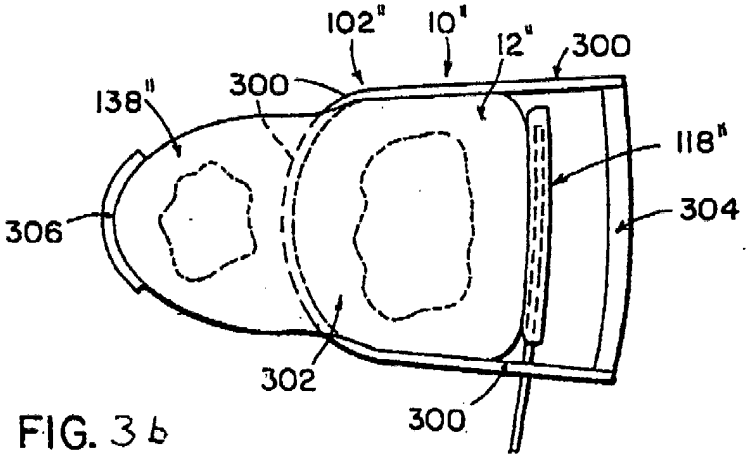

FIG. 3b

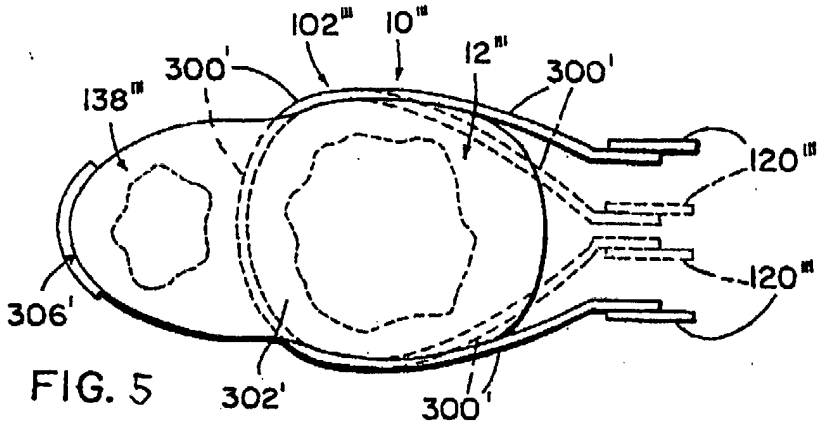

FIG. 5

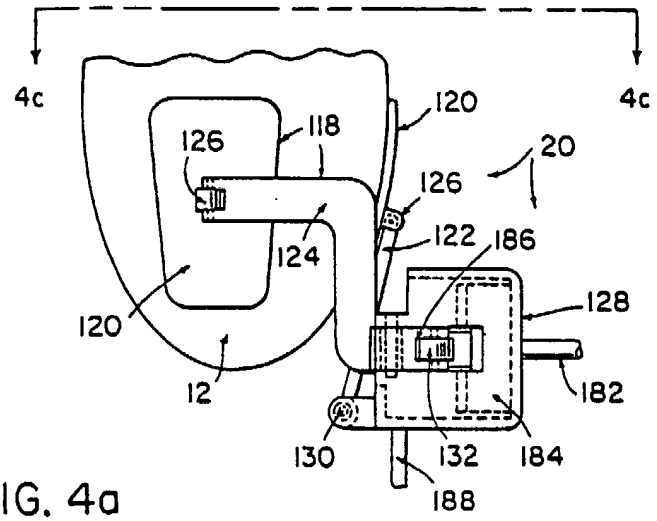

FIG. 4a

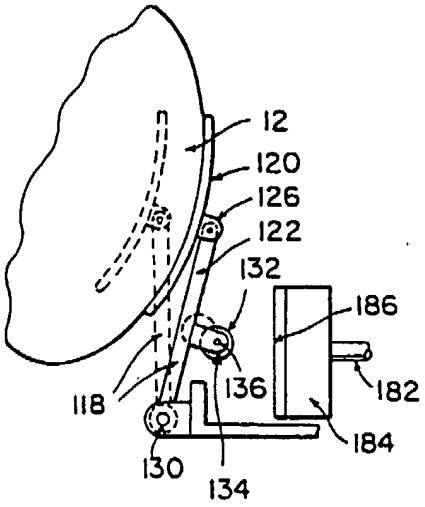

FIG. 4b

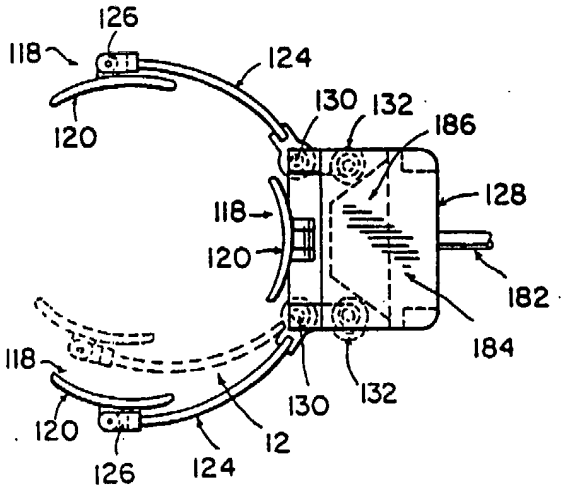

FIG. 4c